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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,252	07/08/2003	Stephen James	13425-137001/BV-1026 US	8190

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EXAMINER	
BULL, CHRISTOPHER	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 11/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/615,252	JAMES ET AL.	
	Examiner	Art Unit	
	Christopher Bull	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Abbr.: HDAC2 = histone deacetylase 2, and IRS-1 = insulin receptor substrate 1.

Claims 1-29 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, and 5, drawn to a method of screening compounds for inhibition of HBAC2 activity or expression, and further for testing *in vivo* activity, classified in class 424, subclass 9.2.

II. Claims 4, 6-10, drawn to a method of screening compounds with known inhibition of HDAC2 activity or expression for *in vivo* activity, classified in class 424, subclass 9.2.

III. Claims 11-17, drawn to a method of screening compounds for binding ability to either HDAC2 or IRS-1, and further testing for *in vivo* activity, classified in class 424, subclass 9.2.

IV. Claims 18-20, drawn to a method of identifying agents that increase acetylation of IRS-1, and further testing *in vivo* activity, classified in class 424, subclass 9.2.

V. Claims 21-26, drawn to a treatment of diabetes or insulin resistance based on administering HDAC2 inhibitors, classified in class 514, subclass 866.

VI. Claims 27-29, drawn to a treatment of diabetes or insulin resistance based on administering agents that increase acetylation of IRS-1, classified in class 514, subclass 866.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have distinct functions and methods. The function of the methods of Group I is to identify inhibitors of HDAC2 and further screen them for *in vivo* activity, whereas the function of the methods of Group II is to test compounds with known HDAC2 inhibitory activity for *in vivo* activity. Implicit in the methods of Group I is a step of assessing whether the screened compounds decreased HDAC2 activity or expression, which is not present in the methods of Group II. Therefore, the inventions are unrelated.

Inventions I-II (distinct methods) and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions differ in their mode of operation. The methods of Groups I and II requires compounds that become identified as, or are known as, inhibitors of HDAC2 activity or expression. The methods of Group III assess binding ability to either HDAC2 or IRS-1, and further test for *in vivo* activity. Compounds that bind either of these proteins need not be inhibitors of their enzymatic activities, and compounds which inhibit the expression of a protein need not bind to that protein. Therefore, the inventions are unrelated.

Inventions I-III (distinct methods) and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions again have differing modes of operation. The methods of Groups I and II involve HDAC2 activity or expression, and those of Group III involve only binding to HDAC2 or IRS1 polypeptides, whereas the methods of Group IV involve testing whether the compounds increase the acetylation of IRS-1. As above, compounds which bind need not alter activity and *vice versa*, and compounds active towards HDAC2 need not be active towards IRS-1. Therefore, the inventions are unrelated.

Inventions I-IV (distinct methods) and V or VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups V or VI are not screening methods, but rather treatments of mammals with compounds that inhibit HDAC2 activity or expression, or increase IRS-1 acetylation. Therefore, the inventions are unrelated.

Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions involve different modes of operation. Those of Group V involve agents that inhibit HDAC2 activity or expression, whereas those of

Group VI involve agents that increase IRS-1 acetylation. Agents that increase IRS-1 acetylation need not be inhibitors of HDAC2 activity or expression, and *vice versa*. . Therefore, the inventions are unrelated.

The required searches for each group are not coextensive and would be burdensome if combined. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Election of Species

This application contains claims directed to two patentably distinct sets of species of the claimed invention.

Claims 2, 3, 7, 8, 14 and 23 are generic to a plurality of disclosed patentably distinct species comprising the following two sets:

Set 1 (see claim 7) "wherein the candidate agent is a peptide, peptidomimetic, amino acid, amino acid analog, polynucleotide, polynucleotide analog, nucleotide, or nucleotide analog.";

Set 2 (see claim 3) "wherein the candidate agent is a hydroxamic acid derivative, cyclic tetrapeptide, benzamide, of butyrate.".

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each of these two sets, even though this requirement is traversed. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit

evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. Currently the following are generic: in Group I Claims 2 and 3; in Group II Claims 7 and 8; in Group III Claim 14; in Group V Claim 23.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Conclusions

No claims are allowed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Bull whose telephone number is (571) 272-1327. The examiner can normally be reached on 7:30-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Bull
Patent Examiner
Art Unit 1655

cb

CHRISTOPHER R. TATE
PRIMARY EXAMINER